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(54) Fluid flow transfer and apparatus and methods associated therewith

(57) A fluid flow chamber cassette (10) that can be mounted with either its front wall or rear wall against a supportin(machine and has a flexible tube (32) that extends from a sidewall and forms a loop that is symmetrical about a loop axis that is transverse to the side wall so that the loop will be acted upon by a pump roller on the machine both wher the front wall is against the machine and when the rear wall is against the machine. Also disclosed is automatically fixing the initial liquid levels and amounts of air in venous and arterial chambers (16, 14) of fluid flow transfer device apparatus by having the arterial chamber inlet (28) enter the arterial chamber (14) at a position higher than the arteri chamber outlet (30), having the venous chamber inlet (47) enter the venous chamber at a position higher than the venous chamber outlet (50), and priming the apparatus by causing reverse flow, so that the liquid rises in the venou: and arterial chambers (16, 14) to the level of the entrances of the inlets (28, 47). Also disclosed is sensing pressure of fluid in a fluid flow chamber by placing an impermeable flexible diaphragm over a hole in a rigid wall of the fluid flov chamber, providing a second chamber on the other side of the diaphragm, and sensing the pressure in the second chamber.

FIG. 1

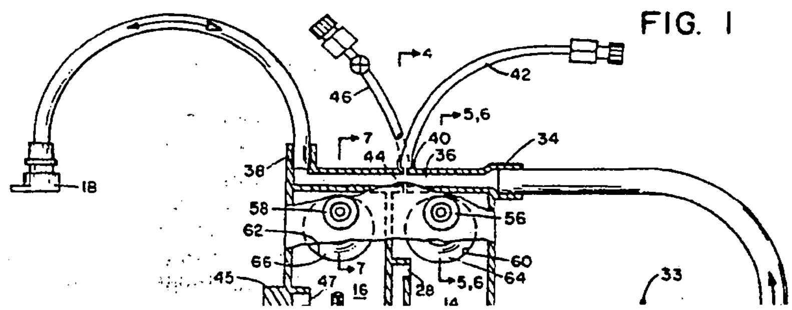

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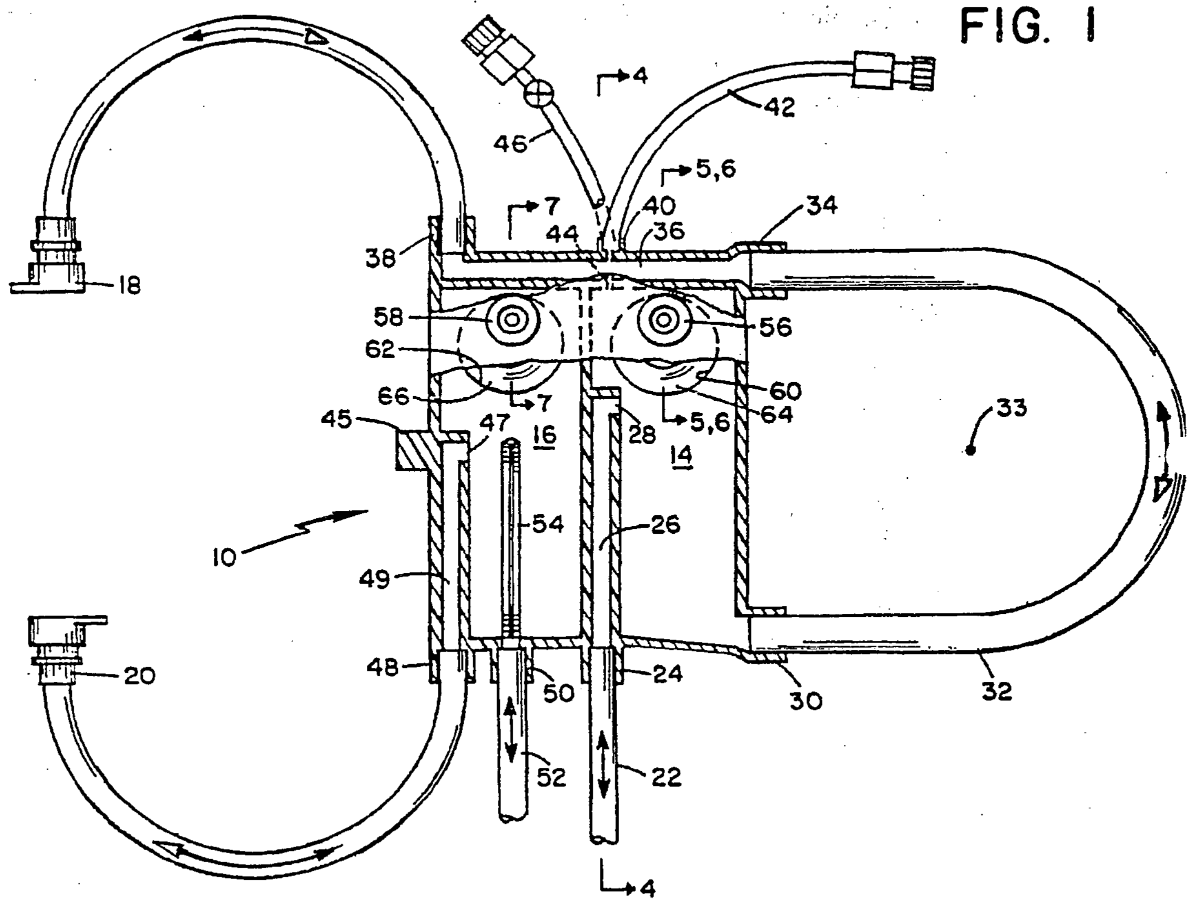
FIG. I



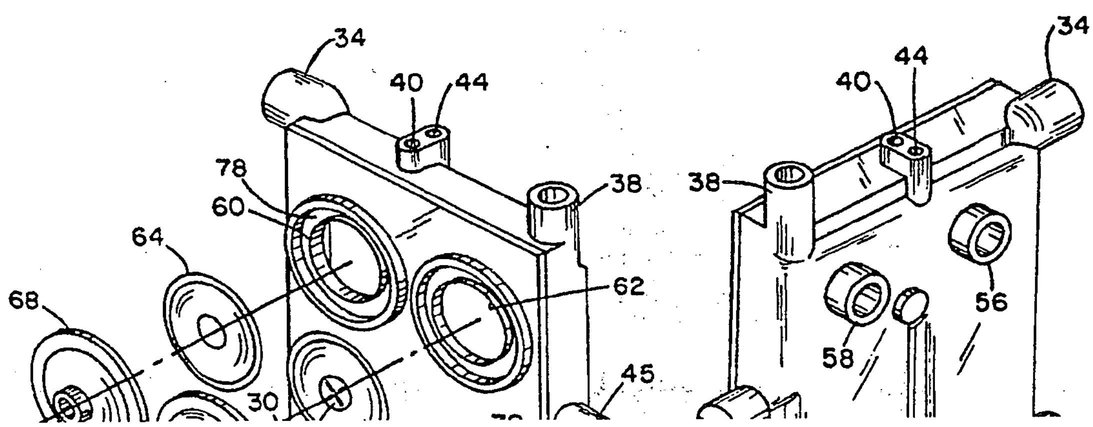


FIG. 4

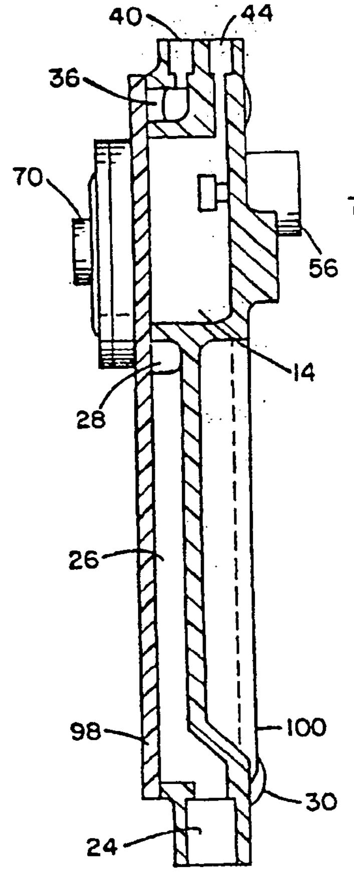
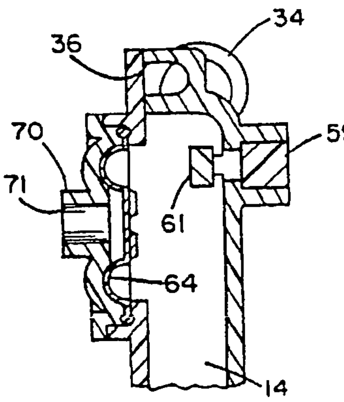


FIG. 5



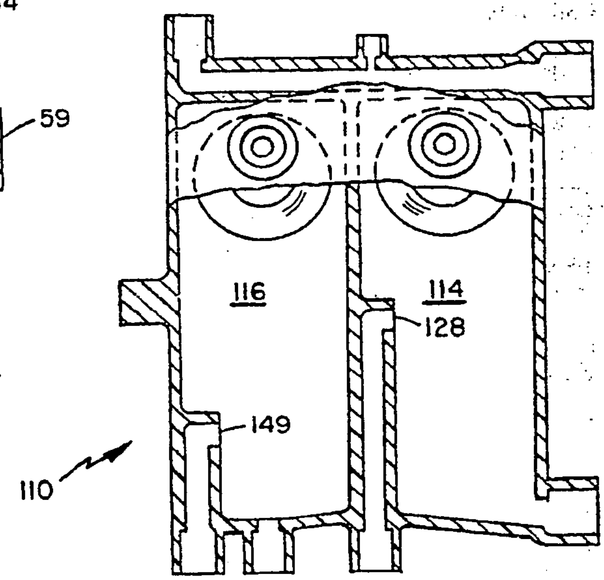
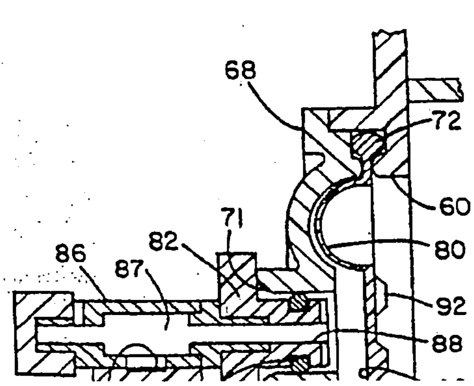
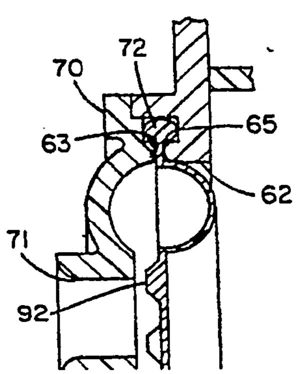
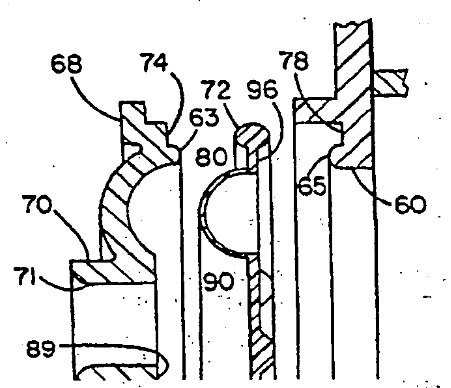


FIG. 9







SPECIFICATION

Fluid Flow Transfer and Apparatus and Methods Associated Therewith

The invention relates to apparatus useful with fluid flow transfer devices such as dialyzers and methods of using the apparatus.

Fluid flow transfer devices such as dialyzers are used to continuously remove impurities from a patient's blood. The blood is typically pumped through tubes and arterial and venous bubble traps of disposable tubing sets connecting the patient to a dialyzer mounted on a dialysate preparation and supply machine.

Bellotti et al. U.S. Patent No. 4,263,808 discloses, as a tubing set replacement, a one-piece hydraulic circuit that includes arterial and venous bubble trap chambers in which blood enters at entrances above the bottoms of the chambers and leaves near the bottoms of the chambers. Pressure in the chambers can be determined by transducers placed against impermeable latex membranes covering holes communicating with upper portions of the chambers.

In one aspect of the invention features a fluid flow chamber cassette that can be mounted with either its front wall or rear wall against a supporting machine and has a flexible tube that extends from a side wall and forms a loop that is symmetrical about a loop axis that is transverse to the side wall so that the loop will be acted upon by a pump roller on the machine both when the front wall is against the machine and when the rear wall is against the machine. The orientation of the cassette and the direction of fluid flow through the cassette can thus be changed by simply changing whether the front or the rear wall is mounted against the machine.

In preferred embodiments the flexible tube is connected at one end to a chamber outlet at the bottom of the chamber and at the other end to the inlet of a flow passage in the cassette, which inlet is located at the same distance from the loop axis as the chamber outlet; the cassette has two chambers (arterial and venous chambers) and additional flexible tubes for connecting a dialyzer between the flow passage and the venous chamber; the outlet of the venous chamber is at the bottom of the venous chamber; and the inlets to the arterial and venous chambers enter the arterial and venous chambers at locations above the outlets of the chambers. In use with a dialyzer, blood from a patient flows through the arterial chamber, the symmetrical pump loop, and the flow passage to the dialyzer, and from there through the venous chamber and back to the patient. After dialysis has been completed, the cassette and dialyzer are inverted and remounted on position higher than the arterial chamber outlet, having the venous chamber inlet enter the venous chamber at a position higher than the venous chamber outlet, and priming the apparatus by causing reverse flow, so that the liquid rises in the venous and arterial chambers to the levels of the entrances of the inlets, and the amount of air in the chambers remains fixed, even after flow is reversed during normal operation with blood.

In another aspect the invention features sensing pressure of fluid in a fluid flow chamber by placing an impermeable flexible diaphragm over a hole in a rigid wall of the fluid flow chamber, providing a second chamber on the other side of the diaphragm and sensing the pressure in the second chamber.

In preferred embodiments the diaphragm is circular and includes a corrugated portion formed symmetrically about the centre, so that the diaphragm moves with little stretching, and the diaphragm is sufficiently elastomeric so that it returns to its original shape when not restrained from movement; the corrugated portion is semicircular in cross-section; and the fluid flow chamber is provided by a cassette that is removably mounted on a machine carrying a pressure transducer, and the second chamber is defined by a portion of the machine surrounding the transducer and a rigid retainer that covers the diaphragm, is carried by the cassette and has an opening adapted to sealably engage the portion surrounding the transducer on the machine.

Other features and advantages of the invention will be apparent from the following detailed description.

The drawings will be briefly described first.

Fig. 1 is a diagrammatic elevation, partially in section, of a cassette for use with a fluid flow transfer device.

Fig. 2 is a diagrammatic, partially exploded, rear perspective view of the Fig. 1 cassette.

Fig. 3 is a front perspective view of the Fig. 1 cassette.

Fig. 4 is a vertical sectional view, taken at 4—4 o. Fig. 1, of the Fig. 1 cassette.

Fig. 5 is a partial vertical sectional view, taken at 5—5 of Fig. 1, of the Fig. 1 cassette.

Fig. 6 is a partial vertical sectional view, taken at 6—6 of Fig. 1, showing a pressure sensing portion o the Fig. 1 cassette connected to a pressure sensor o a machine on which the Fig. 1 cassette is mounted.

Fig. 7 is a partial sectional view, taken at 7—7 of Fig. 1, showing another pressure sensing portion of the Fig. 1 cassette.

Fig. 8 is an exploded partial sectional view of the Fig. 6 pressure sensing portion.

Fig. 9 is an elevation, partially in section, of

through which blood flows prior to and after passing through a dialyzer connected to dialyzer inflow tube 18 and dialyzer outflow tube 20.

Arterial tube 22 is connected to arterial inlet 24, leading to narrow vertical inflow passage 26 that enters arterial chamber 14 about two-thirds of the way up chamber 14 at opening 28. At the bottom of arterial chamber 14 is arterial outlet 30 connected to flexible tube 32, that forms a loop that is symmetrical about axis 33 and is squeezed by the rollers of a peristaltic pump on a dialysate preparation machine (not shown) on which cassette 10 is mounted in use.

The other end of tube 32 is connected to inlet 34 to channel 36, which extends along the upper portion of cassette 10 and ends at outlet 38, connected to dialyzer inflow tube 18. Heparin port 40 at the top of cassette 10 is connected to heparin tube 42 and leads to channel 36. Saline inflow port 44 is connected to saline tube 46 and leads to the upper part of arterial chamber 14 (Fig. 4).

Dialyzer tube 20 is connected to inlet 48 leading to narrow vertical inflow passage 49 that enters venous chamber 16 about slightly more than one-half of the way up chamber 16 at opening 47. Outlet 50 of venous chamber 16 is connected to venous tube 52. Positioned above and blocking the entrance to outlet 50 is plastic blood filter 54. On the front walls of arterial chamber 14 and venous chamber 16 are access ports 56, 58, which have rubber plugs 59 sealing them shut (Fig. 5). Needle guards 61 prevent needles inserted into plugs 59 from going too far into chambers 14, 16.

Referring to Figs. 2 and 6—8, is seen that back plate 98 has holes 60, 62 to arterial chamber 14 and venous chamber 16 covered by diaphragms 64, 66, which are identical, except that their orientations are reversed. Diaphragm 64, subject to negative pressure in arterial chamber 14, has its semicircular corrugated portion 80 extending away from chamber 14, and diaphragm 66, subjected to positive pressure in chamber 14, has its semicircular corrugated portion extending into chamber 14. Behind diaphragms 64, 66 are diaphragm retainers 68, 70, having cylindrical passages 71 therethrough for receiving cylindrical extensions 82 of pressure sensors 83 mounted on the face of the machine that cassette 10 is connected to in use (Fig. 6). At the peripheries of diaphragms 64, 66 are beads 72 that are squeezed between annular surfaces 74, 76 of retainers 68, 70 and opposing annular surfaces 78 surrounding holes 60, 62. Edge portions 96 of diaphragms 64, 66, are squeezed between lips 63 of retainers 68, 70 and opposing lips 65 surrounding holes 60, 62, thereby forming seals between the surface of cylindrical passage 71 of retainer 70. Semicircular corrugated portion 80 extends around diaphragm 64, is 0.125" (0.3175 cm). in radius at its outer surface and extends 180° about its centre. The opposing surface of retainer 68 has the same radius, but does not extend a full 180° near the centre but ends at surface 89, located 0.065" (0.1641 cm.) above centre portion 90 of diaphragm 64. On the opposite surface of diaphragms 64, 66 are four radial projections 92, useful on diaphragm 66 in the venous chamber to prevent blocking on passage 88. Diaphragm 64 is 0.010" (0.0254 cm.) thick at semicircular portion 80, and is 0.020" (0.0508 cm.) thick at centre portion 90 and edge portion 96 near bead 72. Diaphragm 64 is made of silicone rubber (available under the trade designation MDX4-4515 from Dow Corning) and is nontoxic. Corrugated portion 80 can roll in either direction without stretch or friction, and is sufficiently elastomeric to return to its orginal shape when not restrained from movement by fluid conditions in the chambers.

As is perhaps best seen in Fig. 4, cassette 10 is primarily made of two moulded PVC pieces, flat back plate 98, and front piece 100, in which are formed the ports and walls for the various chambers and passages. Back plate 98 is joined to front piece 100 by solvent bonding. Retainers 68 are similarly solvent bonded to back plate 98.

In use, cassette 10 is snapped onto the dialysate preparation machine (not shown) by clothespin-like clips on the machine that engage projection 45 and the tubular extensions providing arterial outlet 30 and flow passage inlet 34. After back plate 98 of cassette 10 has been brought against the machine and locked into position, extensions 82 of the pressure sensors on the machine are automatically inserted into cylindrical passages 71 of retainers 68, 70, sealing with them at O-rings 84. Looped tube 32 fits around the rollers of a peristaltic pump (not shown) also carried on the front of the machine; the axis of the blood pump intersects loop axis 33.

Referring to Fig. 1, the direction of flow during dialysis is shown by the solid arrowheads, and the direction of flow during priming is shown by the open arrowheads. Prior to use with a patient, cassette 10, its various tubes and the hollow fibre dialyzer connected to them are primed with saline solution by connecting the end of venous tube 52 to a saline bag and operating the pump acting on tube 32 in the direction indicated by the open arrowhead (clockwise direction). This causes the saline solution to be pulled into venous chamber 16. The amount of liquid in chamber 16 is automatically determined by the height of opening 47 at the end of inlet passage 49 from inlet 48. Once the saline solution reaches

arterial chamber 14 is automatically set by the height of opening 28. The saline solution then travels through arterial line 22. Once all the air has been removed from the dialyzer, the arterial line is connected to a needle which has been inserted into the patient and clamped shut. The dialyzer need not be inverted after priming, as was common in the prior practice. Also, because of the self-leveling of fluid in chambers 14, 16, the priming of the apparatus is much quicker than, requires less operator effort than, and is more reliable than the timing-consuming priming of prior blood tubing sets, which priming included manual liquid level adjustments.

A heparine source is connected to line 42, and a saline source is connected to line 46. Heparin is automatically fed into passage 36, to prevent blood clotting in the dialyzer. Because passage 36 is at positive pressure, the heparin will now be drawn into the apparatus at a faster than desired rate. Saline line 46 is maintained in a clamped position and is provided as an emergency supply of additional liquid to be quickly administered to the patient in case of shock.

Blood pump 28 is then operated in the forward (counter-clockwise) direction, drawing blood from the patient into tube 22 and through the passages of cassette 10 and the associated tubes, replacing the saline solution in it by forcing the saline solution out of the end of tube 52. Once cassette 10, the dialyzer, and associated tubes have filled with blood, the blood pump is stopped. The end of venous line 18 is connected to a needle into the patient, and dialysis can then begin with the pump going in the counterclockwise direction, the blood flowing as indicated by the solid arrowheads.

During dialysis the amounts of air within chambers 14, 26 remain constant. Pressure is monitored by pressure sensors 83, which are isolated from the blood flow path by nontoxic diaphragms 64, 66. Chamber 14 is generally at a negative pressure (about −150 mm Hg), and chamber 16 is generally at a positive pressure (about +350 mm Hg). The air spaces in chambers 14, 16 provide compliant volumes to accommodate pressure perturbations caused by the operation of the peristaltic pump. The level in arterial chamber 14 is slightly lower than it was during priming, and the level in venous chamber 16 is slightly higher than during priming, owing to the switching between positive and negative pressure conditions with the change in pump direction. Diaphragm 64 moves without stretch or friction (owing to corrugated portion 80) into chamber 14, causing the pressure in chamber 87 to be equal to that in chamber 14. Diaphragm 66 similarly moves toward retainer 70, associated dialzyer are then inverted, with the fror of cassette 10 being against the machine, and outl 30 being at the top and inlet 34 being at the botton Disinfecting solution is then drawn into tube 22 an through the system by running the pump in a clockwise direction, causing the solution to occup all regions in the circuit. Arterial line 22 and venou line 52 are connected together, and the cassette ar dialyzer can then be stored with the solution, whic will be flushed out prior to reuse on the same patient.

Other Embodiments of the Invention are Feasible

For example, Fig. 9 shows cassette 110 for use ir single needle dialysis. Inlets 149, 128 to venous an arterial chambers 116, 114 are at lower positions (inlet 149 being about one-fourth of the way up fro the bottom and inlet 128 being about one-half of tl way up from the bottom), to provide larger air volumes, to permit the liquid volumes to vary during the arterial and venous phases with small pressure changes.

CLAIMS

1. A fluid flow chamber cassette assembly for mounting on a machine including a peristaltic pun roller moving about a pump axis and means for supporting a fluid flow transfer device, said casset comprising:

a plastic casing having front and rear walls spac from each other and a side wall between said fron and rear walls at one side to partially define a first fluid flow chamber, said casing also having a first chamber inlet to said chamber, and a first chambe outlet from said first chamber formed in said side wall;

a first flexible tube for directing liquid from said first chamber to said transfer device, said first tube forming a portion of a loop adapted to be actated upon by said roller of said peristaltic pump, one er of said first tube being connected to said first chamber outlet and another portion of said loop being secured to said casing so that said loop is symmetrical about a loop axis transverse to said sidewall, said loop axis passing through said pum axis when mounted on said machine; and

mounting means for mounting said casing on sa machine in two positions, the first position being said rear wall against said machine, the second position being said front wall against said machin portions of said loop being on opposite sides of sa loop axis when changed from said first to said second position.

2. The cassette of claim 1, wherein said loop axi is in a horizontal position when said cassette is mounted on said machine, said first chamber outl

passage outlet connected to a second flexible tube for connecting to a fluid flow transfer device, and wherein said first tube is connected to said flow passage inlet.

4. The cassette of claim 3, wherein said cassette has a second chamber having a second inlet and a second outlet, said second inlet being connceted to a third flexible tube for connecting to said fluid flow transfer device.

5. The cassette of claim 3, wherein said cassette has a first access port to said first chamber, and a second access port to said flow passage.

6. The cassette of claim 4, wherein said loop axis is in a horizontal position when said cassette is mounted on said machine, said first chamber outlet is at the bottom of said chamber when said rear wall is mounted against said machine, and said first chamber outlet is at the top of said first chamber when said front wall is mounted against said machine, and wherein said second outlet is at the bottom of said second chamber when said rear wall is mounted against said machine, and said second outlet is at the top of said second chamber when said front wall is mounted against said machine.

7. The cassette of claim 6, wherein the entrance of said first inlet to said first chamber is located above said first outlet when said rear wall is against said machine.

8. The cassette of claim 7, wherein the entrance of said second inlet to said second chamber is located above said second outlet when said rear wall is against said machine.

9. The cassette of claim 3, wherein said mounting means comprises tubular projections that extend from said side wall about axes parallel to said loop axis and provide said first outlet and said flow passage inlet.

10. The cassette of claim 9, wherein said mounting means further comprises a projection extending from said cassette on opposite side from said side wall.

11. The combination of the cassette of claim 4 and a fluid flow transfer device connected to said second flexible tube and said third flexible tube and a machine including a peristaltic pump roller, means for engaging said mounting means, and means for supporting said fluid flow transfer device in two positions, one position being with said flow passage inlet being on top and said first outlet being on the bottom, a second position being with said flow passage inlet being on the bottom and said first outlet being on top.

12. A method of operating fluid flow transfer device apparatus, said method comprising:

providing a fluid flow transfer device, an arterial venous chamber; and

priming the blood flow path of said apparatus by pumping sterile priming solution through said venous chamber, fluid flow transfer device and arterial chamber in the opposite direction from normal operation of said apparatus, namely into said outlet of said venous chamber, whereby said sterile solution rises in said venous chamber to the level of the entrance of said venous chamber inlet, flows upward through said fluid flow transfer device, removing air bubbles in it, and into said arterial chamber, rising in said arterial chamber to the level of the entrance of said arterial chamber inlet, whereby the initial liquid levels and amounts of air in said arterial and venous chamber is automatically fixed at predetermined levels and amounts.

13. The method of claim 12, further comprising connecting the inlet of said arterial chamber to a patient, pumping in the direction opposite to that during said priming until said sterile solution in said apparatus has been replaced by blood, connecting the outlet of said venous chamber to said patient and continuing pumping in the same direction to cause transfer in said device.

14. The method of claim 13, further comprising sensing the pressure in said arterial and venous chambers during said continuing pumping.

15. The method of claim 14, further comprising connecting said inlet of said arterial chamber to a sterile solution, pumping to return blood to said patient, disconnecting said patient, turning said device and arterial and venous chambers upside down, and pumping disinfecting solution in through said venous chamber outlet and through all regions in the flow path of said apparatus.

16. Apparatus for sensing the pressure of a liquid, comprising:

a first chamber having an inlet and an outlet for liquid flowing through said chamber, a rigid wall of said chamber having an opening therethrough;

an impermeable flexible diaphragm sealably covering said opening;

means defining a second chamber sealed to said diaphragm on the other side of said diaphragm from said rigid wall chamber; and

a pressure transducer communicating with said second chamber to sense pressure in it,

whereby changes in pressure in said first chamber cause displacement of said diaphragm to change the volume and pressure in said second chamber.

17. The apparatus of claim 16, wherein said diaphragm is circular and includes a corrugated portion formed symmetrically about the center, so that the diaphragm moves with little stretching, said

said transducer mounted on said machine, and a rigid retainer covering said diaphragm, carried by said cassette and having an opening adapted to sealably engage said portion surrounding said transducer.

20. The apparatus of claim 19, wherein said opening is defined by a cylindrical passage that fits over a cylinder projection including a pressure sensor passage to a subchamber including said transducer.

21. The apparatus of claim 19, wherein said retainer has an inner surface having the same shape as said corrugated portion.

22. The apparatus of claim 20, wherein said diaphragm has ribs facing said cylindrical projection to prevent blocking said pressure sensor passage.

23. The cassette of claim 7, wherein said entrance of said first inlet to said first chamber is located about one-half of the way up said chamber when said rear wall is against said machine.

24. The cassette of claim 7, wherein said entrance of said first inlet to said first chamber is located about two-thirds of the way up said chamber when said rear wall is against said machine.

25. The cassette of claim 8, wherein said entrance of said second inlet to said second chamber is about one-half of the way up said chamber when said rear wall is against said machine.

26. The cassette of claim 8, wherein said entrance of said second chamber is about one-fourth of the way up said chamber when said rear wall is against said machine.

27. A fluid flow chamber cassette assembly having a front wall and a rear wall and adapted for mounting with either its front wall or rear wall against a supporting machine, and further including a flexible tube extending from a side wall of said cassette assembly to form a loop that is symmetrica about a loop axis that is transverse to the side wall such that said loop is located at a position at which i can be acted upon by a pump roller on the machine both when the front wall is against the machine and when the rear wall is against the machine, whereby the orientation of the cassette and the direction of fluid flow therethrough can be changed by simply selecting either the front or rear wall to be mounted against the said machine.

28. A fluid flow chamber cassette assembly substantially as hereinbefore described with reference to and as shown in the accompanying drawings.

29. A method of operating fluid flow transfer device apparatus, which method is substantially as hereinbefore described with reference to the accompanying drawings.

30. Apparatus for sensing the pressure of a liquid, the apparatus being substantially as hereinbefore described with reference to and as shown in the accompanying drawings.

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